

148 (New). The method of claim 146, wherein said antibody is a genetically engineered antibody.

149 (New). The method of claim 146, wherein said antibody or fragment thereof is a single chain monoclonal antibody.

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REMARKS

claims 1-4 and 126-149 presently appear in this case. No claims have been allowed. The present communication is intended to supplement applicant's amendment of December 31, 2001, in light of the interview conducted on August 14, 2002. Consideration of the present supplemental amendment in conjunction with applicant's amendment of December 31, 2001, and examination on the merits and allowance of all the claims now present in the case are respectfully urged.

The interview among Examiners Ungar and Tsang and attorneys Kit and Browdy on August 14, 2002, is hereby gratefully acknowledged. In this interview the issues raised in applicant's amendment of December 31, 2001, were discussed, and the examiners concluded that the form of 37 C.F.R. §1.176, as existed prior to the amendment thereof in the September 8, 2000, rule package, is the wording of the rule which applies to this case. Applicant agrees with this conclusion. This means that the examiners cannot require that applicant file divisional applications, although applicant is not prevented from voluntarily filing divisional applications.

Furthermore, the examiners agreed with applicant's contentions that all of the claims in the case after the amendment of December 31, 2001, are drawn to inventions other than as originally claimed and deleted during prosecution of the application that led to the patent which is now under reissue. In light of the examiners' agreement on the record in the Examiner Interview Summary Form that those claims were not subject to recapture estoppel, applicant advised the examiner that it would voluntarily submit a new set of simplified claims, reducing the number of inventions and species for initial examination on the merits without prejudice toward the continuation of prosecution of the deleted claims in a voluntarily filed divisional.

In accordance with the agreements made at the above-mentioned interview, the present amendment deletes all of the non-original claims which had been pending in the case, and substitutes new claims 126-149. The following table explains the relationship of each new claim to the previously existing claims:

TABLE

New Claim	Replacing Old Claim
126	120
127	17
128	18
129	19
138	101
142	99

New Claim	Replacing Old Claim
143	95
144	96
145	97
146	93
147	89
148	90
149	91

Claims 130-137 and 139-141 are new.

The following statements are made pursuant to the requirements of 37 C.F.R. §1.173(c). Patent claims 1-4 are pending. Added claims 5-125 have been cancelled. Claims 126-149 are newly presented in the present supplemental amendment.

As for an explanation of the support in the disclosure of the patent for the changes made to the claims, claim 126, which replaces claim 120, is directed to a "pharmaceutical formulation", as is supported in the paragraph beginning at line 22 of column 9. That the formulation may comprise an antibody is first supported by the sentence beginning at column 9, line 24. The use of an antibody fragment which binds to the antigen is supported, for example, in the sentence beginning at column 9, line 45. That the antibody may be an anti- $\beta$ -amyloid antibody, is supported by the sentence beginning at column 5, line 51. Support for the term "prevent or reduce aggregation" may be found in the first paragraph of column 6. For the requirement that the antibody or fragment be effective to disaggregate an aggregate of  $\beta$ -

amyloid, see the paragraph beginning at column 5, line 23, and the sentence beginning at column 5, line 40. As to the effective amount, reference is made to the paragraph beginning at column 9, line 7, and the subsequent paragraph. As to the pharmaceutically acceptable carrier, reference is made to the paragraph beginning at column 9, line 22.

As to claim 127, the wording is the same as previously-appearing claim 17. That the antibody (for example, of column 5, line 30) may be a monoclonal antibody is supported, for example, at the paragraph beginning at column 6, line 21.

As to claim 128, the language is the same as that of previously-appearing claim 18. The term "genetically engineered antibody" is supported, for example, in the sentence beginning at column 10, line 1, the first sentence of column 6, and the sentence beginning at column 9, line 45.

Claim 129 is the same as previously-appearing claim 19. Support for single-chain antibodies is found, for example, at the paragraph beginning at column 6, line 27, and the paragraph beginning at column 16, line 34.

As to Claim 130, a method for preventing or reducing aggregation of  $\beta$ -amyloid is disclosed in the first paragraph on column 6. The rest of the language of claim 130 is the same as that which appears in claim 126 discussed hereinabove. Similarly, the language of claims 131-133 is the same as that appearing in claims 127-129 discussed hereinabove.

With respect to claim 134, a method of reversing aggregation is disclosed, for example, in the sentence beginning at column 5, line 40. The rest of the language is the same as that discussed hereinabove with respect to claim 126. Claim 135-137 have the same language as in claims 127-129 discussed in detail hereinabove.

Claim 138 is the same as previously appearing claim 101, rewritten in independent form. Use of the method for treating a subject afflicted with Alzheimer's disease is supported, for example, in the paragraph beginning at column 16, line 27. That Alzheimer's disease is characterized by aggregation of  $\beta$ -amyloid is supported by the paragraph beginning at column 3, line 8. The remaining language of claim 138 is as discussed above with respect to claim 126. Claims 139-141 are the same as claims 127-129 discussed above.

Claim 142 is the same as previously-appearing claim 99, rewritten in independent form. The method of preventing or reducing aggregation of  $\beta$ -amyloid by causing an effective amount of an anti- $\beta$ -amyloid antibody to come into contact with said  $\beta$ -amyloid is supported in the first paragraph of column 6. The remaining language is the same as that appearing in claim 126 which has been discussed above. Claims 143-145 have the same language as claims 127-129 which have already been discussed above.

Claim 146 is the same as previously appearing claim 93, rewritten in independent form. Support for disaggregating an aggregate of  $\beta$ -amyloid in a subject by causing an effective

amount of anti- $\beta$ -amyloid antibody to come into contact with the aggregate is found at column 5, in the paragraph beginning at line 23 and in the paragraph beginning at line 40. That the antibody is an anti- $\beta$ -amyloid antibody is supported by paragraph beginning at column 5, line 51. The remaining language is the same as that which also appears in claim 126 and has been discussed above. Claim 147-149 are the same as claims 127-129, which have already been discussed above.

None of these claims are drawn to the same subject matter as the claims which had originally appeared in application 08/358,786 and were subsequently deleted therefrom following a restriction requirement without any divisional applications having been filed. In the Examiner Interview Summary Record, the examiners agreed that the claims that were present in this case after the amendment of December 31, 2001, were all drawn to inventions other than as originally claimed, i.e., are not subject to recapture estoppel. As the present claims substantially correspond to the inventions claimed as of December 31, 2001, all of the present claims should also be considered to be free of the recapture estoppel doctrine and examined in this case. In the interview, the examiners considered an advance draft of the present claims and agreed that they were all free of recapture estoppel for the same reasons discussed in detail in applicant's amendment of December 31, 2001, and again explained at the interview.

Accordingly, it is submitted that all of the formalities noted in the official action of June 29, 2001,

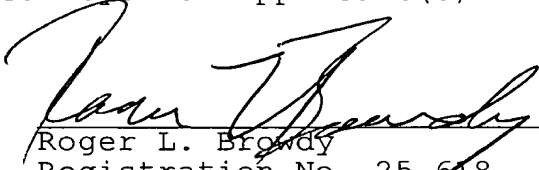
have been resolved and that all of the present claims are in condition for examination on the merits. The present claims are greatly simplified from the claims previously submitted and the present claims are all directed to a single species of anti-aggregation protein ( $\beta$ -amyloid) so as to facilitate examination of the claims which are presently considered to be the most commercially important. Applicant reserves the right to file a divisional application with respect to the generic claims or additional species at an appropriate time.

Accordingly, consideration of the present supplemental amendment in conjunction with applicant's amendment of December 31, 2001, reconsideration and withdrawal of all of the grounds for refusing to act on the merits of the claims from the official action of June 29, 2001, search and examination of all of the claims on the merits, and allowance thereof are earnestly solicited.

Respectfully submitted,

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